EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT CARDIOVASCULAR SYSTEMS, INC. and ABBOTT LABORATORIES, INC., Plaintiffs, v. MEDTRONIC VASCULAR, INC. and MEDTRONIC USA, INC., Defendants.	**REDACTED PUBLIC VERSION** Civil Action No. 98-80 (SLR) (Consolidated with C.A. No. 98-314 (SLR) and C.A. No. 98-316 (SLR))

MEDTRONIC'S SURREPLY IN OPPOSITION TO ABBOTT'S MOTION TO LIFT STAY OF PROCEEDINGS ON ABBOTT'S MOTION FOR PERMANENT INJUNCTION AS TO MEDTRONIC'S ENDEAVOR

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I. INTRODUCTION

Medtronic respectfully submits this surreply to correct two misstatements of fact contained in Abbott's Reply Brief In Support Of Its Motion To Lift Stay Of Proceedings (D.I. 830). Although there are numerous legal and factual errors in Abbott's reply, these two issues in particular require correction because they are fundamentally wrong:

[redacted]

Second, Abbott's characterization of the *eBay* discovery that was previously allowed with respect to the bare-metal stents is categorically wrong. Contrary to Abbott's assertions, there are several categories of discovery relating to the application of the *eBay* factors to Endeavor that: (i) Abbott prevented Medtronic from obtaining during the last round of discovery, and (ii) Medtronic will need to obtain from Abbott (and third parties) to respond to the Injunction Motion against Endeavor.

II. ARGUMENT

[redacted]

2.

[redacted]

3.

[redacted]

[redacted]

1 [redacted]

B. Abbott Prevented Medtronic From Obtaining Necessary *eBay* Discovery Regarding Endeavor

Abbott's claim that additional *eBay* discovery regarding Endeavor is unnecessary is also belied by the record. Notably, Medtronic was not permitted to test the primary evidence Abbott has submitted to date regarding the effect that an injunction of Endeavor would have on the public interest. Abbott had relied on eight paragraphs in the declaration of Dr. Joel Kahn to argue that Medtronic's Endeavor stent was no safer or more efficacious than other drug-eluting stents on the U.S. market. (*See* D.I. 727 at 13; D.I. 830 at 4; *see also* D.I. 730 ¶¶ 8-15.) But prior to Dr. Kahn's deposition, Abbott staked out the position that discovery regarding these paragraphs would not be permitted, because it was "stayed." (*See* D.I. 828 Ex. B ("[T]he Court stayed all discovery related to DES at Medtronic's request – thus staying discovery as to paragraphs 8-15 of Dr. Kahn's declaration . . . .").) Accordingly, Medtronic was not permitted to question Dr. Kahn about the statements or the evidence cited in these paragraphs during his deposition.[2]

Had Medtronic had the opportunity to question Dr. Kahn about this evidence, Medtronic would expect that Dr. Kahn would concede that Endeavor has several design and safety advantages as compared to the currently available drug-eluting stents. Indeed, the medical literature Dr. Kahn relies upon confirms that Endeavor is significantly more deliverable than other drug-eluting stents. (*See* D.I. 730 Ex. 2 at 2446 ("[D]evice success was significantly higher with [Endeavor as compared to Cordis' Cypher], owing to the enhanced stent deliverability likely associated with a more flexible, low profile thin-strut cobalt alloy stent.");

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[2] Medtronic briefly questioned Dr. Kahn about the medical literature referenced in these paragraphs to establish that these articles only are relevant to the drug-eluting stent portion of his declaration. (*See* Deposition Transcript of Joel K. Kahn, M.D., Sept. 15, 2007 at 9:2-25; 11:10-12:7) (Louden Decl. Ex. E).) But Medtronic asked no further questions about the substance of this evidence.

see also Briefing Information for FDA Circulatory System Devices Panel Meeting, Oct. 10, 2007, at 4-55 (noting that "[p]rocedure success rates were higher with the Endeavor stent compared to the Cypher stent (99.4% vs 95.6%) or the Taxus stent (98.7% vs 96.8%).") (Louden Decl. Ex. F).) Moreover, as noted in Medtronic's Answering Brief, Dr. Kahn's evidence indicates that Endeavor may be associated with fewer heart attacks than other drug-eluting stents. (*See* D.I. 828 at 3.) This finding appears consistent throughout the Endeavor clinical program. (*See* Louden Decl. Ex. F at 4-55 (noting that Endeavor was associated with a lower incidence of peri-procedural non-Q wave myocardial infarctions in both ENDEAVOR III – against Cordis' Cypher – and ENDEAVOR IV – against Boston Scientific's Taxus).)

Another crucial category of information that was not provided by Abbott in the last round of *eBay* discovery is information relating to Abbott's own drug-eluting stent, Xience. Abbott repeatedly mentions Xience in the Injunction Motion (*e.g.*, D.I. 727 at 11-12, 17-18), yet Medtronic has not been permitted to conduct discovery concerning this device.[3] Information relating to Xience is relevant not only to the irreparable harm prong of *eBay*, but it is also relevant to both the balance-of-hardships and public interest prongs. In light of concerns raised at the FDA Circulatory System Devices Advisory Panel Meeting in November 2007 that Xience may be associated with an increased incidence of stent thrombosis than other drug-eluting stents, Medtronic expects that additional discovery will reveal, *inter alia*, that patients treated with Endeavor may be at a decreased risk of suffering deadly blood clots than patients treated with Xience. (*See* Transcript of FDA Circulatory System Devices Advisory Panel Meeting, Nov. 29, 2007, at 374 (comments of Dr. John W. Hirshfeld, M.D.) ("[T]here clearly is no decrease in stent

[3] For example, Medtronic limited its prior requests for production to documents relating to the relative safety and efficacy of Abbott's *bare-metal stents*. (*See* D.I. 828 Ex. A at Request No. 18.)

thrombosis, and depending upon which data set you look at, and how you examine it, it's possible that this device [Xience] might have a greater frequency of stent thrombosis than some other devices.") (Louden Decl. Ex. G); *id*. at 518-519 (comments of Dr. John C. Somberg, M.D.) (voting against approval of Xience because "the safety data in the 12 to 24 months was inadequate, and . . . it was of concern to me that with the recent tumult about late stent thrombosis . . . to have inadequate data leaves this issue really unaddressed for many years to resolve.").)

Finally, Medtronic should be permitted to take discovery from third parties, including physicians who would be affected by an injunction against Endeavor. *See, e.g, Cordis Corp. v. Boston Scientific Corp*., 99 Fed. Appx. 928, 935 (Fed. Cir. May 28, 2004) (affirming the district court's determination that the public interest weighed against a preliminary injunction because "the record contain[ed] evidence that some doctors prefer the Taxus stent over the Cypher stent"); *Datascope Corp. v. Kontron Inc*., 786 F.2d 398, 401 (Fed. Cir. 1986) (holding that the trial court did not err in finding that the public interest would be harmed by the grant of a preliminary injunction because the defendant's device – an intraaortic balloon catheter – was preferred by some doctors over the patent holder's device); *Cordis Corp. v. Adv. Cardiovascular Sys., Inc*., No. 97-550, 1998 U.S. Dist. LEXIS 11342, at *31 (D. Del. July 17, 1998) (determining that the public interest would be better served if a preliminary injunction did not issue against ACS's Multi-Link stent where the Multi-Link was "preferred by some physicians" and "may be better suited to some medical circumstances than its competitors"). None of this was addressed in the prior briefing and discovery period relating to the bare-metal stents.

In view of the foregoing additional discovery necessary to respond to Abbott's request for an injunction against Endeavor, due process mandates an additional discovery and

briefing period regarding Endeavor. Whereas Abbott seeks to deny Medtronic the right to take discovery or submit any evidence in opposition to Abbott's Injunction Motion against Endeavor, Abbott has attempted to submit its own lopsided evidence in support of its briefs. (*See, e.g.*, D.I. 730 ¶¶ 8-15.) In fact, Abbott improperly used its reply brief here to submit *additional* evidence – an FDA press release concerning the results of the Endeavor clinical studies (D.I. 831 Ex. 3) – to bolster its purported showing that an injunction against Endeavor would not disserve the public health. (*See* D.I. 830 at 4-5.) As a result, Abbott's reply itself illustrates the need for adequate discovery and briefing on this issue.

III. CONCLUSION

For these reasons, and for the additional reasons set forth in Medtronic's Answering Brief (D.I. 828), Medtronic respectfully requests that the Court deny Abbott's Motion To Lift Stay Of Proceedings On Abbott's Motion For Permanent Injunction As To Medtronic's Endeavor, and enter an order requiring Abbott to file separately against Endeavor. Alternatively, should the Court permit Abbott to accuse Endeavor in this case, Medtronic requests that it be granted six months to take and complete *eBay* discovery from Abbott and various third parties, and an additional sixty days to file its Answering Brief in opposition to Abbott's Injunction Motion against Endeavor.

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April 1, 2008
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EXHIBIT 2 – PART A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT CARDIOVASCULAR SYSTEMS, INC. and ABBOTT LABORATORIES, INC., Plaintiffs, v. MEDTRONIC VASCULAR, INC. and MEDTRONIC USA, INC., Defendants.	**REDACTED PUBLIC VERSION** Civil Action No. 98-80 (SLR) (Consolidated with C.A. No. 98-314 (SLR) and C.A. No. 98-316 (SLR))

DECLARATION OF KAREN JACOBS LOUDEN

Karen Jacobs Louden declares as follows:

1. I am a partner in the law firm of Morris, Nichols, Arsht and Tunnell LLP, counsel to defendants Medtronic Vascular, Inc. and Medtronic USA, Inc. (collectively "Medtronic") in this action.

2. I submit this declaration in support of Medtronic's Surreply to Abbott's Motion to Lift Stay of Proceedings on Abbott's Motion for a Permanent Injunction as to Medtronic's Endeavor.

3. Attached hereto as Exhibits are true and correct copies of the following documents:

Exhibit A. [redacted]

Exhibit B. [redacted]

Exhibit C. [redacted]

Exhibit D. [redacted]

Exhibit E. Excerpts of September 15, 2007 Deposition of Joel K. Kahn, MD.

Exhibit F. Briefing Information for FDA Circulatory System Devices Panel Meeting, Oct. 10, 2007.

Exhibit G. Excerpts of November 29, 2007 FDA Meeting of Circulatory Systems Devices Panel regarding Xience.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 1, 2008
Redacted Filing Date April 11, 2008
2231946

Karen Jacobs Louden
Karen Jacobs Louden

EXHIBIT A

CONFIDENTIAL EXHIBIT

EXHIBIT B

CONFIDENTIAL EXHIBIT

EXHIBIT C

CONFIDENTIAL EXHIBIT

EXHIBIT D

CONFIDENTIAL EXHIBIT

EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT CARDIOVASCULAR SYSTEMS INC. and ABBOTT LABORATORIES INC., Plaintiffs, vs. MEDTRONIC VASCULAR, INC. and MEDTRONIC USA, INC. Defendants.	C.A. No. 98-80 (SLR) (Consolidated with C.A. No. 98-314 (SLR) and C.A. No. 98-316 (SLR))

COPY

The Deposition of **JOEL K. KAHN, M.D.** taken by the Defendants, pursuant to Notice, before Elizabeth A. Tubbert, RPR, (CSR-4248), a Notary Public within and for the County of Oakland, State of Michigan, at 900 Wilshire Drive, Suite 202, Troy, Michigan, on Saturday, September 15, 2007.

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Appearing on behalf of the Defendants

your deposition that are responsive to Request No. 2?

A Correct, there are no others.

MR. VANCE: Counsel, just to clarify something for the record, Dr. Kahn responded to the subpoena subject to the objections set forth in his written responses, and so to the extent the requests were objectionable, unstated objections, the responses and the production was subject to those.

MR. CHUNG: Okay.

Q (By Mr. Chung) Well, taking a look at Exhibit 3 to your deposition, I just want to make sure we go through what's been attached here. The first document is your CV; is that correct?

A Yes.

Q And then the next document is your Declaration, which is, at least in terms of the written content, the same as Exhibit 1 to your deposition here today?

A Right.

Q And that includes as exhibits to it another copy of your CV?

A Yes.

Q As well as an article from the Journal of the American College of Cardiology?

A Yes.

Q Written by David Kandzari, K-A-N-D-Z-A-R-I?

A That's correct.

Q And then the next exhibit to your Declaration, which is attached as an exhibit to Exhibit 3, is an article entitled "Two-year results from ENDEAVOR III point to safety, efficacy"?

A Yes.

Q Then the next document after that is another copy of the Kandzari article. Is that right?

A Right.

Q Followed by another copy of the article entitled "Two-year results from ENDEAVOR III point to safety, efficacy." Do you see that?

A Yes.

Q Then the final document in this group is an article from Circulation, the Journal of the American Heart Association. Is that right?

A That would be correct.

Q So, in essence, you relied on three articles for purposes of preparing your Declaration. Is that right?

A Right. All three of these articles pertain to the drug-eluting stent aspect of my Declaration, which I think is from point 8 and beyond, and the first seven points did not require research articles or books to indicate the opinions.

Q Okay. Did you provide these articles which are part of Exhibit 3 to counsel or did counsel provide them to you?

A I provided them to counsel.

Q And let's take a look at paragraph 7 of your Declaration. The third sentence of your Declaration in paragraph 7 says, "Based on my personal experience, my review of medical literature, and my discussions with colleagues, moreover, Medtronic's stents are no safer or more effective than other stents on the market, such as made by ACS, Boston Scientific, and Cordis." Do you see that?

A Yes.

Q Starting with your personal experience, what in your personal experience led you to conclude that Medtronic's bare-metal stents are no safer or more effective than other stents on the market?

A My placement of their current and prior stent line in patients that I care for. That goes back with Medtronic stents to probably 1988.

Q So that's based on your personal implantation of stents in patients; is that right?

A Right.

Q Did you create any statistical evidence as a result of your personal experience?

A No.
Q Have you conducted any empirical studies of stent use in your personal experience?
A No.
Q Is there anything else in your personal experience that you're relying on in reaching your conclusion that Medtronic's bare-metal stents are no safer or more effective than other stents on the market?
A No.
Q Let's look at your statement regarding your review of medical literature. Do you rely on any of the articles that are attached to Exhibit 3 as the medical literature upon which you rely for the basis of your conclusion in paragraph 7 of your Declaration?
A No, because those articles don't speak to bare-metal stent success rates.
Q So I'm correct that none of these articles that have been produced by your counsel describe any comparisons among bare-metal stents; is that right?
A Correct.
Q In fact, none of these articles say anything about any ACS stent, period; isn't that right?
A That's correct.
Q And none of these articles say anything about a Boston Scientific bare-metal stent; is that right?

A That's true.
Q Nothing about a Cordis bare-metal stent; correct?
A The Cordis bare-metal stent, correct, was not used in these articles.
Q None of these articles say anything about any competitor's bare-metal stent; is that right?
A That's true.
Q So I guess I need to ask you, when you say your review of medical literature in paragraph 7, what exactly are you referring to?
A I'm referring to the fact that I personally subscribe both online and in print form to all leading interventional cardiology journals and I review them whether it's weekly or monthly that they arrive. I participate in journal clubs with cardiology fellows that I train where we review current literature, and in my knowledge of that literature, which comes out of my general practice and my role as a teacher at my hospital, that there is no literature that indicates the Medtronic stents are safer and/or more effective, and, therefore, I didn't bring any because none exist for the current product line or recent product line that indicates that that is the case.
Q Are you aware of any medical literature that actually compares any two bare-metal stents from different